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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,919	08/26/2003	Paul Joseph Dominowski	PC25246	2440
25533 7590 01/16/2009 PHARMACIA & UPJOHN 7000 Portage Road KZO-300-104 KALAMAZOO, MI 49001				
EXAMINER				
HURT, SHARON L				
ART UNIT		PAPER NUMBER		
1648				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/647,919

**Applicant(s)**

DOMINOWSKI, PAUL JOSEPH

**Examiner**

SHARON HURT

**Art Unit**

1648

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-23, 25 and 28-75 is/are pending in the application.
- 4a) Of the above claim(s) 12-19 and 32-75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-23, 25 and 28-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

The amendments to the claims filed October 23, 2008 have been acknowledged and entered. Claim 20 is currently amended.

### ***Status of the Claims***

Claims 12-23, 25 and 28-75 are pending. Claims 12-19 and 32-75 have been withdrawn from consideration. Claims 1-11, 24, 26, 27 and 76-83 have been canceled. Claims 20-23, 25 and 28-31 are under examination.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 1-5, 7-11, 20-23, 25, 27-31, 76-77 and 79-82 under 35 U.S.C. 103(a) as being unpatentable over Bowland et al. and Fulton et al. (Vaccine, 15 September 2000, Vol. 19, No. 2-3, pages 264-274) in view of Brake et al. (US Patent No. 6,787,146, Sep. 2004, Publication 16 May 2002, US2002/0058046) **is maintained for claims 20-23, 25 and 28-31.**

The claimed invention is drawn to an immunogenic and a vaccine composition comprising a modified live Bovine Herpesvirus Virus (BHV-1), a modified live Parainfluenza Virus Type 3 (PI-3), a modified live Bovine Respiratory Syncytial Virus (BRSV), an adjuvant, Bovine Viral Diarrhea Virus Type-1 (BVDV-1), a Bovine Viral Diarrhea Virus Type-2 (BVDV-2) and a veterinary-acceptable carrier, wherein BVDV-1 and BVDV-2 are inactivated, wherein

said adjuvant comprises a saponin, a saponin-containing oil-in-water emulsion, Quil A, lecithin and oil blend, and cholesterol, wherein said adjuvant is microfluidized, wherein the immunogenic and vaccine composition further comprises a *Leptospira* or *Campylobacter fetus* antigen, wherein BVDV-1 and BVDV-2 is cytopathic or noncytopathic.

Bowland et al. discloses current commercial vaccines available in Canada for bovine respiratory disease. Vaccines include infectious bovine rhinotracheitis virus [(IBRV), bovine herpesvirus-1, (BHV-1)], bovine viral diarrhea virus (BVDV), bovine respiratory syncytial virus (BRSV), parainfluenza-3 virus (PI-3), and bacterial antigens including *Leptospira* serovars (page 33 and Table 1 pages 43-45). Some of the multi-vaccines included adjuvants (Table 1, pages 43-45). Bowland teaches the vaccine compositions and intended use of the multi-vaccines.

Bowland et al. do not teach a vaccine composition comprising BVDV types 1 and 2. Bowland et al. do not teach a vaccine composition with an adjuvant comprising Quil A, Amphigen (lecithin and oil blend) and cholesterol.

Fulton et al. (hereinafter Fulton) teaches a vaccine composition comprising BVDV types 1 and 2 (see Table 1, Vaccine 3). Fulton also teaches BVDV has two biotypes, cytopathic (CP) and noncytopathic (NCP) (page 264, 1st column). Fulton further teaches vaccine containing modified live virus (MLV) (page 264, 2nd column).

Brake et al (hereinafter Brake) discloses a vaccine for cattle against bovine Neospora comprising a veterinary acceptable adjuvant comprising SEAM62 (column 8, lines 36-50). SEAM62 is an oil-in-water emulsion containing Quil A, lecithin and cholesterol (column 12, lines 59-67).

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to use BVDV types 1 and 2 for protection against BVDV 1 and 2. The person of ordinary skill in the art would have been motivated to use both BVDV types 1 and 2 because Fulton teaches both types cause disease in cattle, and reasonably would have expected success because of the teachings of Bowland and Fulton.

As set forth in *In re Kerkoven*, 205 USPQ 1069 (CCPA 1980), it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose...the idea of combining them flows logically from their having been individually taught in prior art. In this case, the common purpose is vaccination of cattle against diseases. Furthermore, combination vaccines were already known and used in the art, as discussed above.

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to use an oil-in-water emulsion adjuvant for the immunogenic or vaccine composition. The person of ordinary skill in the art would have been motivated to use an oil-in-water emulsion adjuvant because Brake teaches the preparation is a veterinary acceptable adjuvant, and reasonably would have expected success because of the *in vitro* immunization and challenge in mice experiments described by Brake.

#### ***Response to Arguments***

Applicant's arguments filed October 23, 2008 have been fully considered but they are not persuasive. Applicants argue "Bowland et al. does not teach or suggest a vaccine comprising BVDV types 1 and 2." Fulton teaches a vaccine available at the time the invention was made that comprise BVDV types 1 and 2. Bowland teaches vaccines comprising IBRV, BHV-1,

BVDV, BRSV, PI-3 and bacterial antigens. Applicants argue "Brake et al. only describes a parasite vaccine while Applicant's invention comprises viral and bacterial vaccines." The Brake reference is relied upon to teach different adjuvants commonly used in cattle vaccines.

Applicants argue "while Brake et al. demonstrates that an adjuvant works for a homogenate parasite vaccine, the reference simply does not demonstrate that the adjuvant works in a whole cell viral vaccine, especially where response to whole organism bacteria is also intended." Brake teaches a range of adjuvants commonly used in cattle vaccines which would be obvious to a person skilled in the art to use in a bovine vaccine. Applicants argue "In regard of Fulton et al., the mere fact that the reference discloses a vaccine composition comprising BVDV types 1 and 2 does not render obvious the present invention which is directed to the *simultaneous* provision of numerous immunogenic components from multiple organisms." Fulton teaches bovine vaccines comprising multiple organisms. A person skilled in the art would have the knowledge to customize the components of a vaccine to meet the needs of the cattle industry. "A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton." KSR v. Teleflex, Inc., 82 USPQ2d 1385, 1397 (2007).

With regard to the strict construction and application of the TSM test, Applicant is directed to KSR v. Teleflex, Inc., No. 04-1350 (U.S. Apr. 30, 2007), which states, "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. As our precedents make clear, however, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." (KSR, slip op. at 14). The Court continued, stating that "helpful insights, however, need not become rigid and mandatory formulas; and when it is so applied, the TSM test is incompatible with our precedents. The obviousness analysis cannot be confined by a formalistic

conception of the words teaching, suggestion, and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents." KSR, slip op. at 15. As such, the rejection at issue and its analysis under 103(a) meets all of the *prima facie* requirements under *Graham v. Deere* (1966) (*supra*) and *KSR v. Teleflex* (2007) (*supra*).

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON HURT whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

January 8, 2009

/Bruce Campell/

Supervisory Patent Examiner, Art Unit 1648